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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/585,541 | 06/02/2000 | Reiner Gentz | PF402P1 | 6732 |

22195 7590 07/28/2004

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
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| EXAMINER | |
|---|---|
| SISSON, BRADLEY L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Examiner-Initiated Interview Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/585,541 | GENTZ ET AL. | |
| | Examiner | Art Unit | |
| | Bradley L. Sisson | 1634 | |

**All Participants:**

(1) *Bradley L. Sisson*.

(2) *Mark J. Hyman, Reg. No. 46,789*.

**Status of Application:** *071*

(3) *Karen L. Carroll, Reg. No. 50,784*.

(4) _____.

**Date of Interview:** *14 July 2004*

**Time:** *11:30 AM*

**Type of Interview:**
- ☒ Telephonic
- ☐ Video Conference
- ☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☒ No
If Yes, provide a brief description: .

**Part I.**

Rejection(s) discussed:
*35 USC 112, first paragraph, and 35 USC 103(a)*

Claims discussed:
*1-7 9-33 37-66 71-155*

Prior art documents discussed:
*WO 96/25422 (Human Genome Sciences, Inc.); Chen et al., Journal of Pharmaceutical Sciences, Vol. 85, No. 4, April 1996; US Patent 5,580,856 (Prestrelski et al.); US Patent 6,077,692 (Ruben et al.)*

**Part II.**

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
*See Continuation Sheet*

**Part III.**

- ☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.
- ☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

B. L. Sisson
(Examiner/SPE Signature)

(Applicant/Applicant's Representative Signature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed: Using claim 1 as an example, Mr. Sisson expressed concern over the claims fairly encompassing compositions where the polypeptide does not have any activity. Mr. Sisson noted further that the teachings of Chen et al., while used in the 103(a) rejection, teach at length of how unstable the KGF-2 polypeptide is, and that the Ruben et al., patent also teaches that mature KGF-2 peptide that has additional 5' amino acid residues is inactive. Mr. Sisson suggested these issue could well be overcome by inserting language into the independent claims stipulating that the polypeptide has KGF-2 activity.

The rejection of claims under 35 USC 103(a) was discussed. Mr. Sisson acknowledged applicant's traversal, directing attention to page 36, bridging to page 37 of the resposne received 23 February 2004 (hereinafter the response), where applicant asserts that the prior art of record does not teach using the recited perservatives. Mr. Sisson noted that page 12, paragraph 31, of the Office action of 23 October 203 specifically identifies Prestrelski et al., as teaching the use of "additives" (applicant's "preservatives") methyl and propyl paraben and chlorobutanol, and as such, the prior art fairly teaches this limitation of the claimed invnetion.

Mr. Sisson acknowledged applicant's traversal at page 37 of the response where applicant asserts that Chen et al., effectively teaches away from the claimed invnetion, especially as it relates to claims that recite specific concentrations of additives. Mr. Sisson indicated that Chen et al., was not relied upon s teaching pharmaceuticals, as applicant's own WO publication teaches pharmaceutical preparations of KGF-2. Mr. Sisson noted further that Chen et al., was not necessarily studying pharmaceuticals as the temperature at which his studies were conducted were outside of that encountered in any human, noting with particularity that in Table 1 Chen et al., teach conducting studies between 42 C and 70 C, which correlate with 107 F and 158 F, respectively. Mr. Sisson further noted that in the first sentence of the abstract, Chen et al., teach that KGF-2 is stable in water (zero additives) until it is heated to 37 F, at which point it denatures and aggregates. Mr. Sisson indicated that such a showing, as well as that of Table 1 indicates that lower concentrations of additives are needed when KGF-2 peptides are kept at lower temperatures.

Mr. Hyman suggested adding language to claim 1 whereby concentrations of additives would be positively recited. Mr. Sisson indicated that should such an amendment be made, it would be beneficial if an evidentiary showing could be made that the concentrations of preservatives used are not the result of routine optimization given the various documents cited in the disclosure which teach use of these very components a well as ranges that they are commonly used when the claimed composition arguably comprises these very components at concentration(s) suggested by the art.